

Attorney Docket No. 9701-6
Application Serial No. 09/510,560
Filed: February 22, 2000
Page 2

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application.

1-257. (canceled)

258. (currently amended) A solid oral dosage form which is effective in delivering a drug and an enhancer, each as defined below, to an intestine and which comprises a pharmaceutical composition consisting of:

- (A) a therapeutically effective amount of a hydrophilic or macromolecular drug in the form of crystalline and/or amorphous particles;
- (B) one or more absorption enhancers, each of which: (i) is a solid at room temperature; (ii) is a salt of a medium chain fatty acid having a carbon length of from form 8 to 14 carbon atoms in particulate form; and (iii) is present in the dosage form in a therapeutically effective amount and such that the ratio of the drug to the one or more absorption enhancers is 1:100,000 to 10:1; and
- (C) one or more excipients selected from the group consisting of rate-controlling polymeric materials, diluents, lubricants, disintegrants, plasticizers, anti-tack agents, opacifying agents, pigments, and flavorings.

259. (previously presented) The solid oral dosage form of claim 258, wherein the pharmaceutical composition has thereon an enteric coating.

260. (previously presented) The solid oral dosage form of claim 259, wherein the enteric-coated composition is a tablet.

261. (previously presented) The solid oral dosage form of claim 258, including a capsule which contains said pharmaceutical composition and which has thereon an enteric coating.

Attorney Docket No. 9701-6
Application Serial No. 09/510,560
Filed: February 22, 2000
Page 3

262. (previously presented) The solid oral dosage form of claim 258, wherein:
- (A) the drug is selected from the group consisting of peptides, proteins, oligosaccharides, polysaccharides, and hormones; and
 - (B) the absorption enhancer is selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.
263. (previously presented) The solid oral dosage form of claim 262, wherein the drug is an anticoagulant.
264. (previously presented) The solid oral dosage form of claim 263, wherein the anticoagulant is selected from the group consisting of heparin, low molecular weight heparin, heparinoids, hirudin, and analogues of the foregoing.
265. (withdrawn) The solid oral dosage form of claim 264, wherein the anticoagulant is heparin.
266. (previously presented) The solid oral dosage form of claim 264, wherein the anticoagulant is low molecular weight heparin.
267. (withdrawn) The solid oral dosage form of claim 265, wherein the absorption enhancer is sodium caprate.
268. (previously presented) The solid oral dosage form of claim 266, wherein the absorption enhancer is sodium caprate.
269. (withdrawn) The solid oral dosage form of claim 258, wherein the drug is a bisphosphonate.

Attorney Docket No. 9701-6
Application Serial No. 09/510,560
Filed: February 22, 2000
Page 4

270. (withdrawn) The solid oral dosage form of claim 269, wherein the bisphosphonate is alendronate.

271. (withdrawn) The solid oral dosage form of claim 269, wherein the bisphosphonate is etidronate.

272. (withdrawn) The solid oral dosage form of claim 270, wherein the absorption enhancer is sodium caprate and the ratio of the alendronate to the sodium caprate is 1:1000 to 10:1.

273. (withdrawn) The solid oral dosage form of claim 258, wherein the drug is a peptide.

274. (withdrawn) The solid oral dosage form of claim 258, wherein the drug is a protein.

275. (previously presented) The solid oral dosage form of claim 258, wherein the drug is an oligosaccharide.

276. (previously presented) The solid oral dosage form of claim 258, wherein the drug is a polysaccharide.

277. (withdrawn) The solid oral dosage form of claim 258, wherein the drug is a hormone.

278. (previously presented) The solid oral dosage form of claim 258, wherein the absorption enhancer is sodium caprate.

279. (previously presented) The solid oral dosage form of claim 260, wherein the absorption enhancer is sodium caprate.

280. (withdrawn) The solid oral dosage form of claim 260, wherein the tablet is a sustained-release tablet.

Attorney Docket No. 9701-6
Application Serial No. 09/510,560
Filed: February 22, 2000
Page 5

281. (withdrawn) The solid oral dosage form of claim 280, wherein one of the excipients is a rate-controlling polymeric material.

282. (withdrawn) The solid oral dosage form of claim 281, wherein the rate-controlling polymeric material is hydroxypropyl-methylcellulose.

283. (previously presented) The solid oral dosage form of claim 260, wherein the tablet is an instant-release tablet.

284. (previously presented) The solid oral dosage form of claim 260, wherein the enteric coating comprises a polymer selected from the group consisting of poly(acrylic acid), polyacrylate, poly(methacrylic acid), polymethacrylate, and mixtures thereof.

285. (previously presented) The solid oral dosage form of claim 258, wherein the pharmaceutical composition is in the form of a multiparticulate.

286. (previously presented) The solid oral dosage form of claim 285, wherein the multiparticulate is in the form of a tablet.

287. (withdrawn) The solid oral dosage form of claim 279, wherein the drug is a bisphosphonate.

288. (withdrawn) The solid oral dosage form of claim 279, wherein the drug is heparin.

289. (previously presented) The solid oral dosage form of claim 279, wherein the drug is low molecular weight heparin.

Attorney Docket No. 9701-6
Application Serial No. 09/510,560
Filed: February 22, 2000
Page 6

290. (withdrawn) The solid oral dosage form of claim 258, wherein the pharmaceutical composition includes at least two absorption enhancers.

291. (withdrawn) The solid oral dosage form of claim 258, wherein one of the excipients is a rate-controlling polymeric material.

292. (previously presented) The composition of claim 258, wherein one of the excipients is a diluent which is an inert filler selected from the group consisting of microcrystalline cellulose, lactose, dibasic calcium phosphate, saccharides and mixtures of any of the foregoing.

293. (withdrawn) The composition of claim 292, wherein the inert filler is microcrystalline cellulose.

294. (withdrawn) The composition of claim 292, wherein the inert filler is a lactose selected from the group consisting of lactose monohydrate and lactose anhydrous.

295. (previously presented) The composition of claim 292, wherein the inert filler is a saccharide selected from the group consisting of mannitol, starch, sorbitol, sucrose, and glucose.

296. (previously presented) The composition of claim 295, wherein the saccharide is sorbitol.

297. (previously presented) The composition of claim 258, wherein one of the excipients is a lubricant selected from the group consisting of colloidal silicon dioxide, talc, magnesium stearate, calcium stearate, and stearic acid.

298. (previously presented) The composition of claim 297, wherein the lubricant is stearic acid.

299. (previously presented) The composition of claim 258, wherein one of the excipients is a disintegrant selected from the group consisting of lightly crosslinked polyvinylpyrrolidone, corn starch, potato starch, maize starch and modified starches, croscarmellose sodium, crospovidone, and sodium starch glycolate.

300. (previously presented) The composition of claim 299, wherein the disintegrant is crospovidone.

301. (withdrawn) The composition of claim 299, wherein the disintegrant is polyvinylpyrrolidone.

302. (currently amended) A compressible composition which is capable of being compressed into a solid oral pharmaceutical dosage form which is effective in delivering therapeutically effective amounts of a drug and an enhancer, as defined below, to an intestine, said composition consisting of:

- (A) a therapeutically effective amount of a hydrophilic or macromolecular drug in the form of crystalline and/or amorphous particles;
- (B) one or more absorption enhancers, each of which: (i) is a solid at room temperature; (ii) is a salt of a medium chain fatty acid having a carbon length of from form 8 to 14 carbon atoms in particulate form; and (iii) is present in a therapeutically effective amount and such that the ratio of the drug to the one or more absorption enhancers is 1:100,000 to 10:1; and
- (C) one or more excipients selected from the group consisting of rate-controlling polymeric materials, diluents, lubricants, disintegrants, plasticizers, anti-tack agents, opacifying agents, pigments, and flavorings.

303. (previously presented) The composition of claim 302, in the form of a compressible powder or compressible granules.

304. (withdrawn) The composition of claim 302, wherein one of the excipients is a rate-controlling polymeric material.

305. (withdrawn) The composition of claim 303, wherein one of the excipients is a rate-controlling polymeric material.

306. (previously presented) The composition of claim 302, wherein one of the excipients is a diluent which is an inert filler selected from the group consisting of microcrystalline cellulose, lactose, dibasic calcium phosphate, saccharides and mixtures of any of the foregoing.

307. (withdrawn) The composition of claim 306, wherein the inert filler is microcrystalline cellulose.

308. (withdrawn) The composition of claim 306, wherein the inert filler is a lactose selected from the group consisting of lactose monohydrate and lactose anhydrous.

309. (previously presented) The composition of claim 306, wherein the inert filler is a saccharide selected from the group consisting of mannitol, starch, sorbitol, sucrose, and glucose.

310. (previously presented) The composition of claim 309, wherein the saccharide is sorbitol.

311. (previously presented) The composition of claim 302, wherein one of the excipients is a lubricant selected from the group consisting of colloidal silicon dioxide, talc, magnesium stearate, calcium stearate, and stearic acid.

Attorney Docket No. 9701-6
Application Serial No. 09/510,560
Filed: February 22, 2000
Page 9

312. (previously presented) The composition of claim 311, wherein the lubricant is stearic acid.

313. (previously presented) The composition of claim 302, wherein one of the excipients is a disintegrant selected from the group consisting of lightly crosslinked polyvinylpyrrolidone, corn starch, potato starch, maize starch and modified starches, croscarmellose sodium, crospovidone, and sodium starch glycolate.

314. (previously presented) The composition of claim 313, wherein the disintegrant is crospovidone.

315. (withdrawn) The composition of claim 313, wherein the disintegrant is polyvinylpyrrolidone.

316. (previously presented) The composition of claim 302, wherein:

- (A) the drug is selected from the group consisting of peptides, proteins, oligosaccharides, polysaccharides, and hormones; and
- (B) the absorption enhancer is selected from the group consisting of sodium caprate, sodium caprylate, and sodium laurate.

317. (previously presented) The composition form of claim 302, wherein the drug is an anticoagulant.

318. (previously presented) The composition form of claim 317, wherein the anticoagulant is selected from the group consisting of heparin, low molecular weight heparin, heparinoids, hirudin, and analogues of the foregoing.

319. (withdrawn) The composition of claim 318, wherein the anticoagulant is heparin.

Attorney Docket No. 9701-6
Application Serial No. 09/510,560
Filed: February 22, 2000
Page 10

320. (previously presented) The composition of claim 318, wherein the anticoagulant is low molecular weight heparin.

321. (withdrawn) The composition of claim 319, wherein the absorption enhancer is sodium caprate.

322. (previously presented) The composition of claim 320, wherein the absorption enhancer is sodium caprate.

323. (withdrawn) The composition of claim 302, wherein the drug is a bisphosphonate.

324. (withdrawn) The composition of claim 323, wherein the bisphosphonate is alendronate.

325. (withdrawn) The composition of claim 323, wherein the bisphosphonate is etidronate.

326. (withdrawn) The composition of claim 324, wherein the absorption enhancer is sodium caprate and the ratio of the alendronate to the sodium caprate is 1:1000 to 10:1.

327. (withdrawn) The composition of claim 302, wherein the drug is a peptide.

328. (withdrawn) The composition of claim 302, wherein the drug is a protein.

329. (previously presented) The composition of claim 302, wherein the drug is an oligosaccharide.

330. (previously presented) The composition of claim 302, wherein the drug is a polysaccharide.

331. (withdrawn) The composition of claim 302, wherein the drug is a hormone.

332. (previously presented) The composition of claim 302, wherein the absorption enhancer is sodium caprate.

333. (withdrawn) The composition of claim 302, wherein the composition includes at least two absorption enhancers.

334. (previously presented) A solid oral dosage form which is effective in delivering a drug and an enhancer, each as defined below, to an intestine and which comprises an enterically coated pharmaceutical composition consisting of:

- (A) a therapeutically effective amount of a hydrophilic or macromolecular drug in the form of crystalline and/or amorphous particles;
- (B) sodium caprate, which: (i) is in particulate form; and (ii) is present in the dosage form in a therapeutically effective amount and such that the ratio of the drug to the one or more absorption enhancers is 1:1,000 to 10:1; and
- (C) one or more excipients selected from the group consisting of rate-controlling polymeric materials, diluents, lubricants, disintegrants, plasticizers, anti-tack agents, opacifying agents, pigments, and flavorings.

335. (withdrawn) The solid oral dosage form of claim 334, wherein the drug is a peptide.

336. (withdrawn) The solid oral dosage form of claim 334, wherein the drug is a bisphosphonate.

337. (withdrawn) The solid oral dosage form of claim 336, wherein the bisphosphonate is alendronate.

338. (previously presented) The solid oral dosage form of claim 334, wherein the drug is an anticoagulant.

339. (previously presented) The solid oral dosage form of claim 338, wherein the anticoagulant is low molecular weight heparin.

340. (previously presented) A compressible composition which is capable of being compressed into a solid oral pharmaceutical dosage form which is effective in delivering therapeutically effective amounts of a drug and an enhancer, as defined below, to an intestine, said composition consisting of:

- (A) a therapeutically effective amount of a hydrophilic or macromolecular drug in the form of crystalline and/or amorphous particles;
- (B) sodium caprate, which: (i) is in particulate form; and (ii) is present in a therapeutically effective amount and such that the ratio of the drug to the one or more absorption enhancers is 1:1,000 to 10:1; and
- (C) one or more excipients selected from the group consisting of rate-controlling polymeric materials, diluents, lubricants, disintegrants, plasticizers, anti-tack agents, opacifying agents, pigments, and flavorings.

341. (withdrawn) The composition of claim 340, wherein the drug is a peptide.

342. (withdrawn) The composition of claim 340, wherein the drug is a bisphosphonate.

343. (withdrawn) The composition of claim 342, wherein the bisphosphonate is alendronate.

344. (previously presented) The composition of claim 340, wherein the drug is an anticoagulant.

345. (previously presented) The composition of claim 344, wherein the anticoagulant is low molecular weight heparin.